K101116

JUN 23 2010

510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR §807.92 and the requirements of the Safe Medical Device Act (SMDA) of 1990.

1. Submitter's Name	Abbott Vascular
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3. Telephone	(951) 914-3242
4. Fax	(951) 914-0339
5. Contact Person	Kay Setzer
6. Date Prepared	April 16, 2010
7. Device Trade Name	HI-TORQUE PILOT™ 50, 150, and 200 Guide Wire Family with Hydrophilic Coating
8. Device Common Name	Guide Wire
9. Device Classification Name	Catheter Guide Wire (DQX)
10. Predicate Device Name	HI-TORQUE PILOT Guide Wire (K030549, cleared May 14, 2003)

11. Device Description

The HI-TORQUE PILOT™ Guide Wire with Hydrophilic Coating is a guide wire with a maximum diameter of 0.0140" and is available in a 190 cm extendable length and a 300 cm exchange length.

There are three HI-TORQUE PILOT Guide Wire designs with varying tip stiffness, the HI-TORQUE PILOT 50, HI-TORQUE PILOT 150, and HI-TORQUE PILOT 200 Guide Wires.

The distal tip of the guide wire is available either as a straight tip that is shapeable, or as a pre-shaped "J". The straight shape allows the physician to shape the tip according to his/her preference; the J shapes provide the physician the convenience of a J shape without manual shaping. Brachial and femoral markers are located on the proximal segment of the 190 cm and 300 cm guide wires to indicate when the tip of the guide wire is about to exit the guide catheter.

The proximal section of the wire is coated with polytetrafluoroethylene (PTFE). The distal, polyurethane-covered area of the wire is covered with a hydrophilic coating.

12. Indication for Use

The HI-TORQUE PILOT Guide Wire Family is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The guide wire is also intended to facilitate the placement of compatible stent devices during therapeutic intravascular procedures.

13. Technological Characteristics

Comparisons of the new and predicate devices show that the technological characteristics such as product performance, design and intended use are substantially equivalent to the current marketed predicate devices. The proposed device is similar in design and materials to the currently marketed product in that its core wire, tip coils, and solders remain the same. The hydrophilic coating has been changed but is identical to previously marketed devices.

14. Performance Data

In vitro bench testing, including coating adherence and integrity (particulate testing), and friction testing were conducted on the subject device. These tests were used to verify that the hydrophilic coating has not impacted safety or effectiveness of the device. Other mechanical tests, such as Tensile Strength, Torqueability, Torque Strength, and Tip Flex were leveraged from the predicate device as the mechanical functionality of the device has not changed. Biocompatibility testing was leveraged from predicate devices with identical materials and manufacturing process. Biocompatibility tests included cytotoxicity, hemolysis, acute systemic toxicity, complement activation, coagulation, intracutaneous (intradermal) reactivity test, USP systemic injection test, sensitization, rabbit pyrogen test, LAL pyrogen, bacterial endotoxins, and in vivo thrombogenicity tests. The in vitro bench tests and the biocompatibility tests demonstrated that the HI-TORQUE PILOT Guide Wire met all acceptance criteria and performed similarly to the predicate devices. No new safety or effectiveness issues were raised during the testing program and therefore, the HI-TORQUE PILOT Guide Wire may be considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JUN 2 3 2010

Ms. Kay Setzer
Senior Regulatory Affairs Associate
Abbott Vascular Inc.
26531 Ynez Road
Temecula, CA 92591

Re: K101116
Trade Names: HI-TORQUE WHISPER™ LS, MS, and ES Guide Wire Family With Hydrophilic Coating
HI-TORQUE PILOT™ 50, 150, and 200 Guide Wire Family with Hydrophilic Coating
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: May 27, 2010
Received: May 28, 2010

Dear Ms. Setzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101116

Device Name: HI-TORQUE WHISPER™ LS, MS, and ES Guide Wires with Hydrophilic Coating

Indications for Use:

To facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The wire is also intended to facilitate the placement of compatible stent devices during therapeutic intravascular procedures.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off) 6/23/2010

Division of Cardiovascular Devices

510(k) Number K101116